

REMARKS

This is a response to the Office Action mailed on June 10, 2004, and the references cited therewith.

Claim 19 is amended. Claims 19-22, 24, 34-42 are pending in this application.

The Examiner states that claims 34, 36-39 41 and 42 were withdrawn from consideration. Applicants respond, AS THEY PREVIOUSLY RESPONDED in their amendment dated December 8, 2003, that the Examiner is mistaken. Applicants have not withdrawn these claims from examination. Nor have these claims been the subject of a restriction requirement or any other action that would cause their withdrawal. If the PTO record indicates these claims have been withdrawn, please reinstate them. Applicants request the examination of these claims along with the other pending claims.

The 35 U.S.C. § 103(a) Rejection

The Examiner has rejected claims 19-22, 24, 35, and 40 under 35 U.S.C. § 103(a) as being unpatentable over Takayanagi et al. (Takahanagi) in view of Ventouras et al. (Ventouras). This rejection is respectfully traversed.

Applicants' rejected claims recite a method for treatment of mucosal tissue using pharmaceutical carrier device comprising a layered flexible film having a first water-erodable adhesive layer and a second, water-erodable non-adhesive backing layer. The first layer is adhesive and is free of plasticizer. It typically comprises a film-forming polymer and a bioadhesive polymer. The second layer comprises hydroxyethyl cellulose.

The Examiner asserts that the combination of Takayanagi and Ventouras discloses Applicants' claimed invention because Takayanagi allegedly discloses treatment of oral mucosa with a two layer adhesive medical tape having an adhesive medicament-containing layer and a support layer containing hydroxypropyl cellulose and Ventouras allegedly discloses the equivalence of hydroxypropyl cellulose and hydroxyethyl cellulose as swellable polymers.

First of all, Applicants submit that the Examiner has misquoted Ventouras. Ventouras does not disclose the equivalence of hydroxypropyl cellulose and hydroxyethyl cellulose. The Examiner points to col. 1, lines 48-52 as the passage disclosing this alleged equivalence. However, this passage recites a water-insoluble polymeric substance such as hydroxypropyl

methylcellulose, hydroxyethyl cellulose, hydroxymethyl cellulose, carboxymethylcellulose, sodium carboxymethylcellulose, alginic acid and crystalline cellulose. The Examiner has mistaken the compound “hydroxypropyl **methylcellulose**” for the compound “hydroxypropyl cellulose”.

This mistaken identity is consequential. Hydroxypropyl methylcellulose and hydroxypropyl cellulose are very different materials. Hydroxypropyl methylcellulose is swellable but not soluble in water and is insoluble in alcohol or chloroform. Hydroxypropyl cellulose, however, is soluble in water, alcohol and organic solvents such as chloroform. See the attached page 626 of “Hawley’s Condensed Chemical Dictionary”, Sax and Lewis, Ed’s., Van Nostrand Reinhold, New York, N.Y., 1987. Hence, hydroxypropyl cellulose is not a swellable polymer as asserted by the Examiner.

Second, the Examiner has also misquoted Takayanagi. The Examiner points to Takayanagi at col. 3, lines 61-64 as disclosing Takayanagi’s hydroxypropyl cellulose. This passage discloses no such information. Instead, it is believed that the Examiner meant to refer to the passage at col. 3, lines 3-5, which recites “a water-swellable polymer such as lowly substituted hydroxypropyl cellulose”. Alternatively, the Examiner may have meant the passage col. 2, lines 66-67, which recites “hydroxy-propyl cellulose [in particular a highly substituted one]”.

Both of these Takayanagi recitations refer to the polymer in the medicament or adhesive layer, not the support layer of Takayanagi’s tape. Takayanagi discloses a tape formed of two layers: a medicament-containing layer and a support layer. Takayanagi also calls his support layer an intestine-soluble layer. See col. 2, lines 7-12. Takayanagi’s medicament layer is his adhesive layer while his support layer is non-adhesive. See col. 3, lines 50-60.

The reason why this detail about the layers is important lies in the Examiner’s assertion of equivalence. The Examiner states that the hydroxypropyl cellulose of Takayangi is equivalent to hydroxyethyl cellulose because of Ventouri. Notwithstanding the mistake on which the alleged Ventouri equivalence is based, that statement puts the hydroxyethyl cellulose of Ventouri into the wrong layer. It puts the hydroxyethyl cellulose into the adhesive layer of Takayanagi, and not into the non-adhesive backing layer as Applicants’ claims require. Thus, this art does not provide a disclosure of hydroxyethyl cellulose as a component of a non-adhesive backing

layer as is required by Applicants' claims. Takayangi and Ventouras do not lead to Applicants' claimed invention even if one were motivated to make this combination.

That motivation is lacking also. Applicants respectfully submit that one skilled in the art would not have been motivated to combine the disclosures of Takayanagi and Ventouras. Takayanagi disclose an adhesive medical tape, while Ventouras discloses a tablet. Applicants respectfully submit that one skilled in the art would not look to art related to tablets to modify the backing layer (i.e., support layer) of an adhesive medical tape. Takayanagi's tape is designed to adhere to mucous surfaces. Ventouras tablet is designed to be swallowed, i.e., not adhere to mucous surfaces. Takayanagi's tape has the medicament in a layer on one side and a backing on the other. Ventouras' tablet has a core containing the medicament. His core is completely surrounded by an elastic, water insoluble coating such that it has no ability to adhere. Takayanagi's tape delivers medicament to the oral cavity which Ventouras' tablet does not release medicament until it is in the intestine. Thus, there would have been no motivation to combine the cited documents.

In view of the above remarks, it is respectfully submitted that the claimed invention is patentable over Takayanagi et al. in view of Ventouras. The Examiner is respectfully requested to reconsider and withdraw the rejection of claims 19-22, 24, 35 and 40 under 35 U.S.C. § 103(a), and to allow all claims including claims 19-22, 24, 34-42.

Conclusion

Applicants respectfully submit that the claims are in condition for allowance, and notification to that effect is earnestly requested. The Examiner is invited to telephone Applicants' attorney at (612) 373-6939 to facilitate prosecution of this application.

If necessary, please charge any additional fees or credit overpayment to Deposit Account No. 19-0743.

Respectfully submitted,

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Hawley's
Condensed Chemical
Dictionary

ELEVENTH EDITION

Revised by

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and
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Library of Congress Catalog Card Number: 86-23333
ISBN: 0-442-28097-1

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Printed in the United States of America

Van Nostrand Reinhold Company Inc.
115 Fifth Avenue
New York, New York 10003

Van Nostrand Reinhold Company Limited
Molly Millars Lane
Wokingham, Berkshire RG11 2PY, England

Van Nostrand Reinhold
480 Latrobe Street
Melbourne, Victoria 3000, Australia

Macmillan of Canada
Division of Canada Publishing Corporation
164 Commander Boulevard
Agincourt, Ontario M1S 3C7, Canada

15 14 13 12 11 10 9 8 7 6 5 4 3 2 1

Library of Congress Cataloging-in-Publication Data

Condensed chemical dictionary.
Hawley's condensed chemical dictionary.

Rev. ed. of: The Condensed chemical dictionary.
10th ed./rev. by Gessner G. Hawley, 1981.
1. Chemistry—Dictionaries. I. Hawley, Gessner
Goodrich, 1905— II. Sax, N. Irving (Newton Irving)
III. Lewis, Richard J., Sr. IV. Title.
QD5.C5 1987 540'.3'21 86-23333
ISBN 0-442-28097-1

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monomer used in manufacture of thermosetting acrylic resins for surface coatings.

Properties: A liquid with mw 130.14, bp 77C at 5 torr.

Hazard: TLV: 0.5 ppm in air. Corrosive to skin and eyes. Toxic by skin absorption.

Use: In manufacture of thermosetting resins for surface coatings.

2-hydroxypropylamine. See isopropanolamine.

hydroxypropyl cellulose. CAS: 9004-64-2.

A cellulose ether with hydroxypropyl substitution.

Properties: White powder; soluble in water, methyl and ethyl alcohols, and other organic solvents. Thermoplastic; can be extruded and molded. Insoluble in water above 37.7C. Combustible.

Grade: FCC.

Use: Emulsifier, film former, protective colloid, stabilizer, suspending agent, thickener, food additive.

hydroxypropylglycerin.

Properties: Pale straw-colored liquid, d 1.084 (25/25C), refr index 1.459 (25C), flash p 380F (193C), pour p -23C, soluble in water and methanol. Combustible.

Use: Intermediate for alkyd resins and polyesters, plasticizer for cellulosics, glue, starch, etc.

hydroxypropyl methacrylate.

$\text{CH}_3\text{CHOHCH}_2\text{OOC}(\text{CH}_3)\text{CH}_2$.

Properties: Clear, mobile liquid. D 1.066 (25/16C), refr index 1.446 (25C), flash p 206F (96.6C), limited solubility in water, soluble in common organic solvents. Combustible.

Use: Monomer for acrylic resins, nonwoven fabric binders, detergent lube oil additives.

hydroxypropyl methylcellulose. (methylcellulose; propylene glycol ether).

Properties: White powder, swells in water producing clear to opalescent, viscous, colloidal solution; insoluble in anhydrous alcohol, ether, and chloroform. Combustible.

Grade: NF, FCC.

Use: Food products (except confectionery), as thickening agent, stabilizer, emulsifier; thickener in paint-stripping preparations.

N-β-hydroxypropyl-o-toluidine.

$\text{CH}_3\text{C}_6\text{H}_4\text{NHCH}_2\text{CH}(\text{OH})\text{CH}_3$.

Properties: Amber color, distillation range 170-180C (20 mm), d 1.035-1.045 (20/20C), refr index 1.540-1.550 (20C).

Use: Dye intermediate.

4-hydroxy-2H-pyran-3,3,5,5(4H,6H)tetramethanol. See anhydroenneaheptitol.

2-hydroxypyridine-N-oxide. Bactericidal agent related to aspergillic acid, made from pyridine-N-oxide.

1-hydroxy-2-pyridine thione. (2-pyridinethiol-1-oxide). $\text{C}_5\text{H}_4\text{NOH(S)}$. Apparently exists in equilibrium with the -SH form. Forms chelates with iron, manganese, zinc, etc.

Use: fungicide, bactericide.

4-hydroxy-2-pyrrolidinecarboxylic acid.
See hydroxyproline.

8-hydroxyquinoline. (8-quinolinol; oxyquinoline; oxine). CAS: 148-24-3. $\text{C}_9\text{H}_6\text{NOH}$.

Properties: White crystals or powder, darkens when exposed to light, technical grade usually tan; almost insoluble in water; soluble in alcohol, acetone, chloroform, benzene, also in formic, acetic hydrochloric, and sulfuric acids and in alkalies; phenolic odor; mp 73-75C; bp 267C.

Grade: CP, technical.

Hazard: Toxic by ingestion.

Use: Precipitating and separating metals, preparation of fungicides, chelating agent, disinfectant.

8-hydroxyquinoline benzoate. CAS: 86-75-9. $\text{C}_9\text{H}_6\text{NOH} \cdot \text{C}_6\text{H}_5\text{COOH}$.

Properties: Yellowish-white crystals with a saffron odor, mp 56-61C, almost insoluble in water, soluble in alcohol and glycerol.

Use: Antiseptics, fungicide, recommended against Dutch elm disease.

8-hydroxyquinoline sulfate. CAS: 134-31-6. $(\text{C}_6\text{H}_7\text{NO}_2)_2 \cdot \text{H}_2\text{SO}_4$.

Properties: Pale yellow powder, slight saffron odor, burning taste, melting range 167-182C, soluble in water, slightly soluble in alcohol, insoluble in ether.

Use: Antiseptic, antiperspirant, deodorant, fungicide.

4-hydroxysalicylic acid. See β -resorcylic acid.

12-hydroxystearic acid. CAS: 106-14-9.

$\text{CH}_3(\text{CH}_2)_5(\text{CHOH})(\text{CH}_2)_{10}\text{COOH}$. A C_{18} straight chain fatty acid with an -OH group attached to the carbon chain, mp 79-82C. It is produced by hydrogenation of ricinoleic acid. Combustible.

Use: Lithium greases, chemical intermediates.

1,12-hydroxystearyl alcohol. (1,12-octadecanediol). A long-chain fatty alcohol made by re-

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